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TRANSMITTAL FORM

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Application Number	10/623,360
Filing Date	07/18/2003
First Named Inventor	LEE
Art Unit	1746
Examiner Name	EL ARINI, ZEINAB
Attorney Docket Number	DCS-9176

ENCLOSURES *(Check all that apply)*

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  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
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Firm Name	DADE BEHRING INC		
Signature	Leland K Jordan		
Printed name	LELAND K JORDAN		
Date	MAY 29, 2007	Reg. No.	36,560

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Signature	Leland K Jordan		
Typed or printed name	LELAND K JORDAN	Date	MAY 29, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Ching-Cherng Lee et al.)
)
Serial No.: 10/623,360) Group Art Unit: 1746
)
Date Filed: 07/18/2003) Examiner: El Arini, Zeinab
)
Title: Method For Selectively Washing)
Used Reaction Cuvettes in an Automatic Analyzer)
)
Atty. Docket No.: DCS-9176)

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APPEAL BRIEF PURSUANT TO 37 C.F.R. §1.191

Sir:

Applicants file this Appeal from the decision of the Examiner to the Board of Patent Appeals and Interferences in furtherance to the Notice of Appeal mailed on April 11, 2007, and received by the Patent Office on April 13, 2007.

1. Real Party in Interest. The real party in interest in this appeal is the assignee of the application, Dade Behring Inc.

2. Related Appeals and Interferences. Applicants submit that there are no appeals or interferences currently pending or presently intended that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

3. Status of Claims. Claims 1-14 were in the case originally filed on July 18, 2003, as Ser. No. 10/623,360.

Claims 1 and 12 were first amended on July 14, 2005 to overcome a rejection under 35 USC 102(b) as being anticipated by Choperena et al (US 5,380,487) and to

overcome a rejection under U. S. C. §112, second paragraph. Claims 3 and 5 were amended on July 14, 2005 to overcome a rejection under 35 USC 103(a) as being unpatentable over Choperena et al in combination with Sakagami (US Patent 4,785,407) and Jordan (US Patent 4,325,910).

In response to a restriction requirement, Claims 6-11 were withdrawn from further consideration as being drawn to a non-elected invention.

In a Request for Continuing Examination filed April 4, 2006, Claims 1 and 12 were amended to overcome a final rejection under 35 USC 102(b) as being anticipated by new references, Bell (US 5,679,309) and Devlin (US 2004/0115095 A1).

Claims 2-5, 13 and 14 were rejected under 35 USC 103(a) as being unpatentable over Bell or Devlin et al in combination with Sakagami (US Patent 4,785,407) and Jordan (US Patent 4,325,910).

Amended Claims 1 and 12 were amended on December 1, 2006, to overcome a rejection under U. S. C. §112, second paragraph and under 35 USC 103(a) as being unpatentable over Bell (US 5,679,309) in combination with Sakagami (US 4,785,407) and Jordan (US 4,325,910).

Claims 1-5 and 12-14 are the subject of this appeal and stand finally rejected under 35 USC 103(a) as being unpatentable over Bell (US 5,679,309) in combination with Sakagami (US 4,785,407) and Jordan (US 4,325,910).

4. Status of Amendments. Claims 1 and 12 now on appeal were last amended on December 1, 2006. The claims are set out in Appendix 1.

5. Summary of Claimed Subject Matter. The subject matter claimed in the present application is useful in automated biochemical analyzers that employ a combination of analyte specific chemical reagents and reaction monitoring means to assay or determine the presence or concentration of a specific analyte within a liquid sample suspected of containing that particular analyte. There is increasing pressure to reduce analyzing cost-per-reportable result, and a logical approach is to reuse reaction cuvettes

that have been washed or otherwise cleaned after first reactions are completed therein and then between subsequent reaction assays. Unfortunately, known washing techniques may not be fully capable of restoring a cleaned used cuvette to the degree of cleanliness of an unused cuvette, permitting residue from a prior reaction assay to possibly remain in a washed reaction cuvette. Certain highly sensitive assays have been discovered to have inaccurate results if certain reagent residues from preceding reaction assays are present in a cleansed reaction cuvette. One solution is to simply use a new reaction cuvette for each new assay; however, this defeats the desire to obtain a lower cost-per-reportable result by advantageously washing and reusing reaction cuvettes.

Applicants have provided an automated wash station for cleansing a used reaction cuvette that is operated such that whenever certain "exceptional" assays are scheduled to be next performed in a reaction cuvette, the used reaction cuvette is automatically subjected to an additional cleansing or cleaning operation. (The terms "cleaning and cleansing" including washing, rinsing, and drying.) The particular objective of selective cleaning of a used reaction cuvette is partially achieved by providing a number of washing and drying manifolds, each of which is independently selectively activated to perform or not perform a cleaning operation, depending upon the identity of the assay scheduled to be next performed in that as-yet reaction cuvette.

A critical and inherent characteristic of Applicant's claimed cleansing method is to "look ahead" to determine the assay yet to be performed in a cuvette yet to be cleansed and to vary the cleansing operation according to whatever assay is identified. In particular, Applicant's cleanse a used reaction cuvette with either a first or a second different series of cleansing operations depending upon what assay is scheduled to be next performed in the to-be-cleaned, used cuvette.

To perform this variable cuvette washing scheme, used cuvettes are automatically cleaned by cuvette wash station 67 of the present invention, like seen in FIG. 6, comprising a number of washing manifolds 84, a number of drying manifolds 86, and a number of waste manifolds 88. As seen in FIGs. 7, 9 and 10, each washing manifold 84 and drying manifold 86 is further associated with a washing probe solenoid 84S and a drying probe solenoid 86S, respectively. Wash station 67 is therefore operated with independent selective activation of individual washing probe solenoids

84S and drying probe solenoids 86S so that a used reaction cuvette can be cleansed differently depending upon what assay is scheduled to be next performed in the to-be-cleaned, used cuvette..

6. Grounds of Rejection to be Reviewed on Appeal. Whether or not claims 1-5 and 12-14 are patentable under 35 USC 103(a) over Bell (US 5,679,309) in combination with Sakagami (US 4,785,407) and Jordan (US 4,325,910).

7. Arguments.

a) Grouping of claims. There is a single rejection being appealed which applies to claims 1-5 and 12-14. Applicants understand and acknowledge that claims 1-5 and 12-14 shall stand or fall together.

b) Claims 1-5 and 12-14 stand rejected under 35 U.S.C. §103(a) as being unpatentable under 35 USC 103(a) over Bell (US 5,679,309) in combination with Sakagami (US 4,785,407) and Jordan (US 4,325,910). These rejections are respectfully traversed. The following arguments are directed at the patentability of claims 1 and 12 since Claims 2-4 and 13-14 depend therefrom and further limit the claimed invention.

The feature relied upon for non-obviousness of the present invention is the fact that Applicant's wash station is operated to "look ahead" to determine the identify of an assay yet to be performed in a cuvette yet to be cleansed and to vary the cleansing operation according to whatever assay is identified. Accordingly, whenever certain "exceptional" assays are scheduled to be next performed in a reaction cuvette, the used reaction cuvette is automatically subjected to an additional cleansing or cleaning operation

It is Applicants' position that the present invention is patentable over Bell (US 5,679,309) in combination with Sakagami (US 4,785,407) and Jordan (US 4,325,910) for the simple reason that Bell only discloses increasing analyzer throughput by providing first and second reagent add probes along the periphery of a rotary reaction carousel. Reaction

cuvettes are the "paired up" such that when one cuvette of a member-pair is at a reagent add probe, the other cuvette of the member-pair is at a wash station. This arrangement allows for "opportunistically washing" of a used cuvette (for which analysis is completed) to take place simultaneously with the addition of reagent to a target cuvette (Col. 3, lines 51-54. By adding a second reagent add probe so that reagent can be added to a target cuvette at either of two separate locations on a reaction carousel (Col. 3, lines 32-33), Bell "increases the frequency at which opportunistic washing can take place."

The frequency of washing is increased (Col. 3, lines 63-65) because "a first wash complement" (basically a first used cuvette needing to be washed) may be positioned at the wash probe when reagent is added at the first reagent add probe (Col. 3, lines 35-38) or a different used cuvette needing to be washed (a "second wash complement") may be positioned at the wash probe when its corresponding member-pair is located at the second reagent add probe. This is all that is disclosed at Col. 3, lines 32-58.

For example, as described at Col. 10, lines 20-30, Bell specifically teaches positioning a cuvette requiring reagent at whichever of two reagent add probes places a used cuvette ready for "opportunistic washing" at the wash probe. For example:

At Event 1, Cuvette C1 is positioned at reagent add station R1 and a corresponding Cuvette C2 is parked at wash station WS.

At Event 2, Cuvette C1 is instead positioned at reagent add station R2 and a corresponding different Cuvette C3 is parked at wash station WS.

> "the processor identifies cuvettes 24 which are available for reactant addition in comparison to the inventory of wash-ready cuvettes. Based upon this comparison, the processor determines whether to add reactant at either the first or second reactant addition points which will locate, during the same park cycle, a wash-ready cuvette at the wash point."

If neither Cuvette C2 nor Cuvette C3 are ready to be washed, Bell teaches "Do Not Wash Cuvette" (114 in FIG. 5). In brief, Bell only discloses placing a cuvette at a first

reagent add probe if that placing so positions its corresponding member-pair at a wash probe and placing the cuvette at a second reagent add probe if such placing does not position its corresponding member-pair at a wash probe. This simple increases the opportunity for "opportunistic washing" of used cuvettes.

Bell thus discloses only a single wash process and nowhere is this wash process said to be dependent upon the assay to be next performed in a cuvette to be washed. According to Bell, Col. 3, lines 3-6 and 21-24:

> Each cuvette, according to the menu of the analyzer, is designated to receive a selected reactant and a selected sample for reaction and analysis and, post-analysis, be washed for re-use.
>
> Provided about the reaction carousel is a wash point having a single probe operated to engage, empty and wash a cuvette which is presented at the wash point during a park cycle.

Details about the operation of the wash station are provided at Col. 7, line 62-Col. 8, line 4, as follows:

> The wash station probe 62 is raised and lowered to be received by a cuvette 24 parked at the wash point 61 to aspirate the contents of the processed sample from the cuvette 24, inject and thereafter aspirate a cleaning solution, inject and aspirate rinse solution and wipe the sidewalls of the cuvette 24 to clean the cuvette 24 for processing further samples. Thereafter the wash probe 62 is raised from the cuvette 24 and readied to engage subsequent cuvettes 24 which register and are parked at the wash point 61.

The Examiner errs in suggesting that Col. 5, lines 21-26 teach "dependent upon the assay . . . to be run on a sample and its assay sequence, washing may vary from assay to assay." Bell does state the well known fact that different assays may require different lengths of time for processing as follows (Col 5, lines 20-26):

> dependent upon the assay selected from the menu to be run on a particular sample and its assay sequence, the time necessary to process the cuvettes from additions of the reactant(s), sample, analysis, secondary additions (if required) and washing may vary from assay to assay.

Bell is thus totally silent about "looking ahead" to see what assay will be next performed within a used cuvette and then accordingly adjusting the cuvette cleansing operation as is claimed by Applicant. Applicant specifically claims:

> cleansing a used reaction cuvette such that whenever an assay in a first group of assays is scheduled to be next performed in the cuvette (determined by "looking ahead"), then using a first series of cleansing operations . . . but whenever an assay in a second group of assays is scheduled to be next performed in the cuvette (determined by "looking ahead"), using a different cleansing operations.

The Examiner states that "examining the identify of assays and then cleansing the cuvette by either a first or a second series of cleansing operations" is inherent in Bell. Applicant respectfully disagrees. Bell does inherently identify the assays to be performed on samples and scheduling the analyzer to carry out the various operations in accord with how the assay is to be performed. (Col. 5, lines 23-25) However, all Bell recognizes is that "the time necessary to fully process the cuvettes from reagent addition(s), sample, analysis, secondary additions and washing may vary from assay to assay".

It is not even clear that Bell's analyzer can accommodate a first and a different second series of cleansing operations. The "general cycle scheduling for the analyzer" is disclosed at Col. 8, lines 14-54, along with Fig. 4, and this scheduling generally builds a worklist by examining the requisite reagent add times, sample addition, secondary processing, retesting, and additional samples. This generates a specific indexed pattern of spinning and parking and there is no allowance is provided for varying the wash process while parked.

At Col. 7, line 50 to Col. 8, line 4, Bell describes the operation of wash station 60 as comprising:

1) wash station probe 62 is raised and lowered to be received by a cuvette 24 parked at the wash point 61;

2) aspirate the contents of the processed sample from the cuvette 24;
3) inject and thereafter aspirate a cleaning solution;
4) inject and aspirate rinse solution; and,
5) wipe the sidewalls of the cuvette 24 to clean the cuvette 24 for processing further samples.
6) Thereafter the wash probe 62 is raised from the cuvette 24 and readied to engage subsequent cuvettes 24 which register and are parked at the wash point 61.

Because all of these operations must be completed within the indexed time the cuvette is parked, it appears that Bell's wash station is adapted for only one series of standardized cleansing operations. It is definitely clear that Bell does not disclose two different series of cleansing operations.

Therefore, it is not possible in Bell to "look ahead" to see what assay will next be performed in a cuvette yet to be cleansed and to appropriately modify the cleansing operation which is an essential in Applicant's claimed invention.

The Examiner is saying that Applicant's invention is obvious because the elements required to practice the invention exist in Bell's analyzer. However, Bell only teaches that one of two different cuvettes may be "opportunistically washed" in a wash station that has only disclosed cleansing protocol.

In the Office Action dated February 22, 2007, finally rejecting Applicant's invention, the Examiner states on page 3, "It would have been obvious for one skilled in the art to repeat the washing and rinsing to achieve optimum results." However, Since Bell does not disclose identifying the assay scheduled to be next performed in a (used) cuvette before cleaning it and then using different cleansing operations depending on whether the assay is in a first or second group, Bell cannot be said to anticipate independent claims 1 and 12.

The Examiner turns to Sakagami for teaching detecting the dirtiness level of a cuvette and rewashing a cuvette having dirtiness above a threshold level (Col. 5, lines 14-32). The Examiner also cites Jordan for teaching washing and drying a cuvette and discharging wash liquid (Col. 12, lines 45-48; Col. 13, lines 12-17) and concludes that it would have been obvious for one skilled in the art to use the wash-dry-discharge steps taught by Jordan in the dirtiness detecting scheme taught by Sakagami in Bell et al's, cleaning process to "improve the cleaning process."

As discussed above, Bell does not "look ahead" to see what assay will be next performed in a used cassette that is to be cleaned and adjust the cleaning operation accordingly, as claimed in claims 1 and 12. In addition, Bell has a single washing protocol and there is never a mention of changing washing operations. Consequently, the proposed modification of Bell using the Sakagami and Jordan references fail to teach Applicant's used cuvette washing scheme in which different washing conditions are employed to wash a used cuvette depending upon the identify of the assay scheduled to be next performed therein.

The significance of the Examiner's statement that "The assays as claimed are inherent in Bell system." is not fully understood. Certainly Bell's analyzers can perform assays. However, as explained above, "looking ahead" to ascertain the identity of the particular assay to be next performed in a cuvette to be cleaned and to vary the cleaning conditions depending upon the assay to be next performed therein is a key element of the present invention.

As explained herein, Applicant respectfully submits that the combination of Bell, Devlin et al, Sakagami and Jordan do not anticipate nor render claims 1 and 12 obvious because no combination of the references teach Applicant's method for cleansing a used reaction cuvette with either a first or a second different series of cleansing operations depending upon what assay is scheduled to be next performed in the to-be-cleaned, used cuvette. Furthermore, the differences in the claim over the applied references, and the proposed modification of the applied reference cannot replicate Applicant's cleaning method.

c) Conclusion In view of the above remarks, Applicant respectfully submits that the Examiner has provided no supportable position or evidence claims 1-5 and 12-14 are unpatentable under 35 USC 103(a) over Bell (US 5,679,309) in combination with Sakagami (US 4,785,407) and Jordan (US 4,325,910). Accordingly Applicants respectfully request that the Board find claims 1-5 and 12-14 patentable over prior art of record and withdraw all outstanding rejections.

Respectfully submitted,

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Date: May 29, 2007

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8. CLAIMS APPENDIX

Listing of Claims:

1. (amended) A method for cleansing a used reaction cuvette such that whenever an assay in a first group of assays is determined to be scheduled to be next performed in the cuvette by examining an identify of assays yet to be performed, the cuvette is cleansed by a first series of cleansing operations and whenever an assay in a second group of assays is determined to be scheduled to be next performed in the cuvette by examining the identify of assays yet to be performed, the cuvette is cleansed by a second different series of cleansing operations.

2. (original) The method of claim 1 wherein the first group of assays comprises assays previously determined to potentially have inaccurate assay results if reaction residues in a cleansed used cuvette are greater than a known value and wherein the second group of assays comprises assays previously determined to not potentially have inaccurate assay results if reaction residues in a cleansed used cuvette are greater than the known value.

3. (previously presented) The method of claim 1 wherein the cleansing operations comprise a series of mini-washes followed by vacuum drying the cuvette.

4. (original) The method of claim 1 wherein the first series of cleansing operations includes more cleansing operations than the second series of cleansing operations.

5. (previously presented) The method of claim 3 wherein the assays involve potentially harmful agents and residue from the mini-washes is discharged into a first secure storage and wherein the assays involve biological or innocuous chemical agents and residue from the mini-washes is discharged into a second secure storage.

6-11. (withdrawn)

12. (amended) A method for cleansing a used reaction cuvette such that whenever an assay in a first group of assays is determined to have been previously performed in the cuvette by examining an identify of assays already performed, the cuvette is cleansed by a first series of cleansing operations and whenever an assay in a second group of assays has been previously performed in the cuvette by examining the identify of assays already performed, the cuvette is cleansed by a second different series of cleansing operations.

13. (previously presented) The method of claim 12 wherein the cleansing operations comprise a series of mini-washes followed by vacuum drying the cuvette.

14. (original) The method of claim 12 wherein the first series of cleansing operations includes more cleansing operations than the second series of cleansing operations.

9. EVIDENCE APPENDIX

None

10. RELATED PROCEEDINGS APPENDIX

None